4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-N-0352]

Secura Bio, Inc.; Withdrawal of Approval of New Drug Application for FARYDAK (Panobinostat) Capsules, 10 Milligrams, 15 Milligrams, and 20 Milligrams

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of the new drug application (NDA) for FARYDAK (panobinostat) Capsules, 10 milligrams (mg), 15 mg, and 20 mg, held by Secura Bio, Inc., 1995 Village Center Circle, Suite 128, Las Vegas, NV 89134. Secura Bio, Inc. has voluntarily requested that FDA withdraw approval of this application and has waived its opportunity for a hearing.

DATES: Approval is withdrawn as of [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

FOR FURTHER INFORMATION CONTACT: Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993-0002, 301-796-3137, Kimberly.Lehrfeld@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

On February 23, 2015, FDA approved NDA 205353 for FARYDAK (panobinostat) Capsules, 10 mg, 15 mg, and 20 mg, in combination with bortezomib and dexamethasone for the treatment of patients with multiple myeloma who have received at least two prior regimens, including bortezomib and an immunomodulatory agent, under the Agency's accelerated approval regulations, 21 CFR part 314, subpart H. The accelerated approval of FARYDAK (panobinostat) Capsules, 10 mg, 15 mg, and 20 mg, for multiple myeloma included a required postmarketing trial intended to verify the clinical benefit of FARYDAK.

On September 24, 2021, FDA published the *Federal Register* notice "Oncologic Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments," announcing that FARYDAK (panobinostat) Capsules would be discussed at an Oncologic Drug Advisory Committee Meeting (ODAC) scheduled for December 2, 2021 (86 FR 53067). On November 19, 2021, FDA met with Secura Bio, Inc. to discuss the planned ODAC meeting. The topics discussed included the lack of initiation of the postmarketing trial intended to verify clinical benefit.

On November 22, 2021, Secura Bio, Inc. submitted a letter asking FDA to withdraw approval of NDA 205353 for FARYDAK (panobinostat) Capsules, 10 mg, 15 mg, and 20 mg, pursuant to § 314.150(d) (21 CFR 314.150(d)) and waiving its opportunity for a hearing. In the letter, Secura Bio, Inc. stated they are requesting withdrawal of approval of the NDA for FARYDAK because it was not feasible for them to complete the required postmarketing clinical trials. On November 26, 2021, FDA acknowledged Secura Bio, Inc.'s request for withdrawal of approval of the NDA and waiver of its opportunity for hearing. FDA also cancelled the ODAC meeting scheduled for December 2, 2021, since the applicant's withdrawal request made discussion at an advisory committee meeting moot.

For the reasons discussed above, and in accordance with the applicant's request, approval of NDA 205353 for FARYDAK (panobinostat) Capsules, 10 mg, 15 mg, and 20 mg, and all amendments and supplements thereto, is withdrawn under § 314.150(d). Distribution of FARYDAK (panobinostat) Capsules, 10 mg, 15 mg, and 20 mg, into interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a) and 331(d)).

Dated: March 18, 2022.

Andi Lipstein Fristedt,

Deputy Commissioner for Policy, Legislation, and International Affairs,

U.S. Food and Drug Administration.

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